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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,082	04/07/2006	Jianjun Zhang	089889-000000US	4080

20350 7590 02/07/2008

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,082	ZHANG ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/10/07.

The amendment filed 09/10/07 affects the application, 10/541,082 as follows:

1. Claims 1-6, 8-10, 12-16 have been amended.

2. The responsive to applicants' amendments is contained herein below.

Claims 1-16 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "A method comprising: providing an extract of Coeloglossum viride (L.) Hartm. var. bracteatum (Willd.) Richter; and utilizing the extract in the manufacture of drugs for preventing or treating dementia", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Dependent claim 9 is also encompassed by this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 12 and 13, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43

USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a method for preventing or treating dementia, the method comprising: providing a derivative of a succinate esters ester of a given general formula (I). The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicants claims are drawn to a method for preventing dementia, the method comprising: providing a derivative of a succinate esters ester of a given general formula (I), which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said diseases, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the prevention of such diseases which includes alzhemier's disease, vascular dementia, learning and memory obstacle, dementia related to head injury, and central nervous system infection; and substance-induced delirium does not have a single recognized cause. In fact, the aforementioned diseases, is recognized as having

many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) alcoholism (2) certain metabolic or hormonal disorders (3) brain disorders (4) substance intoxication and (5) family history of said disease. These are only a few of the factors that promote these diseases in people. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. It should be noted that claims 2-5, 12 and 13 which are drawn to a method of preventing the said diseases are also encompassed by the aforementioned rejection.

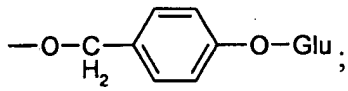
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kizu et al. (Chemical & Pharmaceutical Bulletin (1999) Vol. 47, No 11, pages 1618-1625).

In claim 6, applicant claims "A pharmaceutical composition, comprising an effective amount of any one of the compounds according to claim 1 and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is not water. In claim 7, applicant claims "The pharmaceutical composition according to claim 6, characterized in that said pharmaceutical composition may be in the form of tablets, capsules, pills, injectable solutions, sustained released formulation, controlled released formulation and various microparticle systems. In claim 14-16 are drawn to said pharmaceutical composition, comprising an effective amount of any one of the compounds and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is not water.

Kizu et al. disclose a pharmaceutical composition, comprising the compound according to claim 1 and a pharmaceutically acceptable carrier (water) wherein the compound is dactylorhin B which represents a compound of formula (I) wherein $R_1 = R_4 =$  ; R_2 = -O-Glu; R_3 = -OH and R_5 = isobutyl (a branched C_4 alkyl (see page 1621, compound (7) and page 1624, 2nd col., last paragraph). Kizu et al.'s pharmaceutical composition comprises a dactylorhin B (compound (7)) in H_2O (water) (see page 1624, 2nd col., last paragraph). Furthermore, Kizu et al. pharmaceutical composition is characterized in that the said pharmaceutical composition in the form of an injectable solution (see page 1624, 2nd col., last paragraph). In addition, Kizu et al. suggest that their compounds of can be used as pharmaceuticals and tonic (page 1618, 1st paragraph).

The difference between applicant's claimed composition and the composition taught by Kizu et al. is that Kizu et al. is the type pharmaceutical carrier.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Kizu et al.'s composition comprising the dactylorhin B and to use common pharmaceutically acceptable carrier other than water, such as ethanol and methanol, in order to use it as a drug or tonic, depending on factors such as the type and severity of the condition treated, the type of individual treated and the intended route or means of administration.

One having ordinary skill in the art would have been motivated, to prepare Kizu et al.'s composition comprising the dactylorhin B and to use common pharmaceutically acceptable carrier other than water, such as ethanol and methanol, in order to use it as a drug or tonic, depending on factors such as the type and severity of the condition treated, the type of individual treated and the intended route or means of administration. It should also be noted that the use of different formulations (such as tablets capsules and injectable solutions) comprising active ingredients such as dactylorhin B is common in the art and is well within the purview of a skilled artisan.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Yaoxue Xuebao (2002), Vol. 37, No. 3, pages 199-203).

In claim 10, applicant claims "A pharmaceutical composition, comprising an effective amount of extracts according to claim 8 and a pharmaceutically acceptable carrier, wherein said pharmaceutically acceptable carrier is not ethanol. In claim 11, applicant claims "the pharmaceutical composition according to claim 10, characterized in that said pharmaceutical composition may be in the form of tablets, capsules, pills, injectable solutions, sustained released formulation, controled released formulation and various microparticle systems

Huang et al. disclose a pharmaceutical composition, comprising an extract (of Coeloglossum viride (L.) Hartm. var.bracteatum (Willd.) Richter) according to claim 8 and a pharmaceutically acceptable carrier (ethanol) (see abstract). Huang et al. disclose a pharmaceutical composition, comprising an extract (of Coeloglossum viride (L.) Hartm. var.bracteatum (Willd.) Richter) according to claim 10 and a pharmaceutically acceptable carrier (ethanol) in the form of an injectable solution (see abstract).

The difference between applicant's claimed composition and the composition taught by Huang et al. is that Huang et al. is the type pharmaceutically acceptable carrier.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Huang et al.'s composition comprising Huang et al.'s compound(s) and to use common pharmaceutically acceptable carrier other than water, such as ethanol and methanol, in order to use it as a drug or tonic, depending on factors such as the type and severity of the condition treated, the type of individual treated and the intended route or means of administration.

One having ordinary skill in the art would have been motivated, to prepare Huang et al.'s composition comprising Huang et al.'s compound(s) and to use common pharmaceutically acceptable carrier other than water, such as ethanol and methanol, in order to use it as a drug or tonic, depending on factors such as the type and severity of the condition treated, the type of individual treated and the intended route or means of administration. It should also be noted that the use of different formulations (such as tablets capsules and injectable solutions) comprising active ingredients such as Huang et al.'s compound(s) is common in the art and is well within the purview of a skilled artisan. It should be noted that applicant's claim to foreign priority over

China 02159342.6 (12/21/2002) has not been perfected, since an English translation of the said foreign priority document is not filed.

Response to Amendments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

2/4/08

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

February 3, 2008.